Design and test of a semi-automated system for metrological verification of non-contact clinic thermometers

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Design and test of a semi-automated system for metrological verification of non-contact clinic thermometers.

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Abstract. Clinic thermometers are, probably, the most used measurement instrument in the medical facilities (hospitals, clinics, etc.) all around the world. A good part of the assessment the physician does on the patient's health status will depend on the result of such a measurement. In this work, a system to assess the quality of non-contact clinic thermometers is developed and presented; the accuracy of the system is designed to be a useful tool in the phase of the instrument verification and as a base for a future automated calibration facilities.

1. Introduction

It is in some way surprisingly that there is commonly no habit, nor protocols, for metrological calibration and verification of the instruments used in hospitals in most parts of the world in its daily use. In Spain, our group is trying to create a committee of the standard metrological bodies with the aim to suggest "good practice" guidelines in this field and, in the long run, a possible regulation on metrological assessment of medical instrumentation used in hospitals. The newly founded committee is working on a directive of medical instrumentation systems, the related IEC or ISO standards, and on an assessment of the calibration and/or verification procedures implanted at the user facilities (clinics, hospitals, daily care centers).

The high turnover of some of the instruments (like, for example, thermometers) or the high cost of others require a time-effective procedure for the verification, easy to be carried out by the available personnel, and that will not incur in a strong added cost to the instrument (cost that, one way or another, would be passed on the final user, the patient).

To start with a simplified set of instruments to study, the group has decide to approach three kind of medical instruments and to analyse them with respect to metrological characteristics and verification need: the clinic thermometers, the ECG systems, and the cardiovascular pressure measurement systems. The work on the clinical thermometers is oriented to study two kinds of devices: direct contact (skin) thermometers, and no-contact instant thermometers.

One of the authors, as director of quality control in the rehabilitation hospital of FREMAP, Majadahonda, Madrid, set up a verification system for the calibration of the skin-contact clinical thermometer used daily in the hospital facilities [1]; a system for verification of the calibration point of

the devices has been designed and built; this system is currently in use in the aforementioned hospital and is part of the periodic verification procedure of the facility's quality control.
On the other hand, the usage of no-contact thermometers is on the rise, giving the much more practical handling, especially in the case of forehead thermometers (as opposed to in-ear versions), which can be used without any kind of physical contact with the patient and therefore safer under the cross-contamination risk.
In this paper we will present the design of a non-expensive, easy-to-use, verification system for the "instant" no-contact clinic forehead thermometers, thought to be added to clinical facilities scheduled quality control procedures in a straightforward way.

2. System design and implementation

2.1. Stating the problem
The available literature on calibration and verification of near-IR no-contact thermometers is somehow biased towards the analysis of Infra-red Ear Thermometers (IET), for which analysis of different calibration setups are available [2],[3]. Infra-red Forehead Thermometers (IFT) seems to be less studied. Indeed the measurement system used in the case of IETs has clear advantages versus the IFTs method: the measurement is performed in a closed space, with a lot less variability introduced by external factors, and with a black-body approximation of the emitting surface much more at hand.
In the case of IFTs, the measurement is performed by approximating the sensing end of the device (typically an IR diode with or without some optic contraption) to the skin of the patient's forehead, and slightly moved --- to average or maximize the radiation received, depending on the algorithm implemented on the specific brand). The device must compensate for different skin thermal characteristics (that although studied quite extensively present a high variability [4]), radiation differences [5] and, in addition, ambient temperature variations [6]. This is the reason why IFT are widely considered less reliable and "accurate" than skin-contact of IET replacement.
Nevertheless, IFT devices are easier to use, do not require (if well handled) any contact with the patient skin (so that they can be freely used in consecutive manner on a high number of patients without any hygienic concern), and allow the personnel to scan a big number of patients in short periods --- useful for example for massive scanning in school or airports. The daily usage of these devices in medical facilities will be helped by an effective, fast and economically viable system able to periodically verity the correct behaviour of the thermometer.

2.2. System design
In Fig. 1 the system under development is sketched up as it will be when in final production. The whole system will be highly portable, with an approximate size of 30x10x20 cm, possibly operated by battery. It will have a USB computer connection for remote control and data dump and firmware upgrades. The controlling unit is based on a microcontroller unit PIC30F3010, which has deemed sufficient for the task of controlling the "target" part of the device.
The target is the real heart of the system. It is basically a sloping surface which will simulate the skin emissivity at various temperatures under the control of the CPU unit. The structure of the target is shown in more detail on the left side of the same figure.

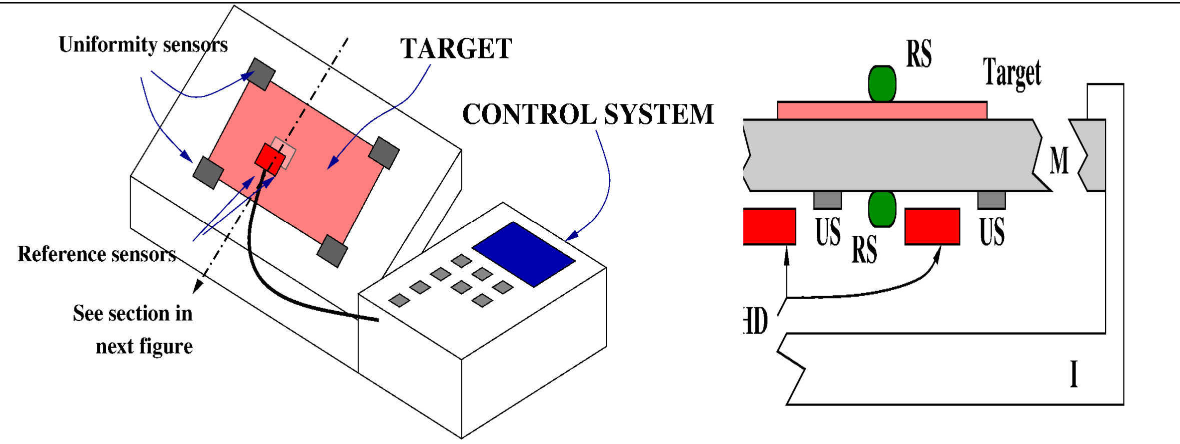

Figure 1. Structure of the proposed system (right), detail of the target (left, detailed description in the main text).

The target is composed by an highly thermally conductive metallic sheet, M, enclosed by one side with a thermal insulator (styrofoam or similar). The metallic sheet is heated by a set (four in the first prototype) of power transistors, controlled with pulse width modulation (PWM) directly by the microcontroller. On the central zone of the target, several low-cost temperature sensors (LM35 or similar) are bond to the metallic sheet; in order to check the uniformity of temperature on the target with the help of a pre-calibration made with a thermal IR camera. On the upper side of the metal sheet, where the thermometer under test (TUT) will be pointed to, a material simulating the reflectance of human skin will be layered upon the surface. Two reference sensors, one fixed on the lower side of the target sheet, and another one movable on the upper side, will be used as the source of the reference body temperature. The selected component is an AD592 sensor, calibrated in the 35-45 ºC range with the help of the CEM (Spanish Center for Metrology, Tres Cantos, Spain).
The system will be calibrated in two phases. In the first phase, the low-precision sensors will be cross-calibrated to teach the system when the metal sheet can be considered at uniform temperature, using a IR thermal camera to check it in the first pass, and the movable reference sensor after that.
In the second phase, the system will be fully calibrated at the CEM facilities with a pyrometer system.
The finished system is, at the date of the writing of this article, in the state of advanced prototype; just the case and the (optional) batteries operated power supply is missing. The user interface is still rudimentary, as the analysis of the best skin-simulating material to be used in the final prototype, but the system has reached the point where a full set of measurements can be performed with meaningful results.

3. Measurements

3.1. Devices under test
To check the performance of the system, we have verified three different brand's IFT. The three instrument characteristics are described in Table 1. The brands of the three instrument are kept private at this stage, given that the verification board has not been properly calibrated nor the verification procedures has passed any kind of standardization. The data reported in the table has been obtained by the instrument data-sheet.Notice that the data easily available on the instruments' data sheets is the resolution, and not the accuracy.

Table 1. Devices under test.

DEVICE	Brand	*Aproximated Cost (EUR)*	Bought at	*Range (ºC)*	Declared resolution (ºC)
TIF1	B1	40	Pharmacy	32-42.9	0.1
TIF2	B2	80	Pharmacy	34-42.2	0.1
TIF3	B3	15	Internet (e-bay)	N/A	0.1

To verify the correct behaviour of the devices, a set of 5 tests have been performed for each one of the thermometers:

1. A hysteresis test: measurements has been taken with a ramp-like temperature pattern: the target was set to temperatures from 35 to 45 ºC; then the temperature was dropped back from 45 to 35 ºC and, finally, it was raised again to 45 ºC. During the ramps, measurements were obtained for every integer temperature. (TEST. 1)
2. A repeatability test: the target was stabilized at 36.5ºC and each thermometer was tested several times, switching it to off state between each measurement point. (TEST. 2)
3. An inclination sensitivity test in which it was tested the dependency of the measurement with the inclination between the optical axis of the thermometer and the normal to the skin. (TEST. 3)
4. A distance sensitivity test to find the dependence around the usual work conditions of the thermometers. (TEST. 4).
5. An ambient temperature sensitivity test to evaluate the influence of it on the measurement of each thermometer.(TEST. 5)

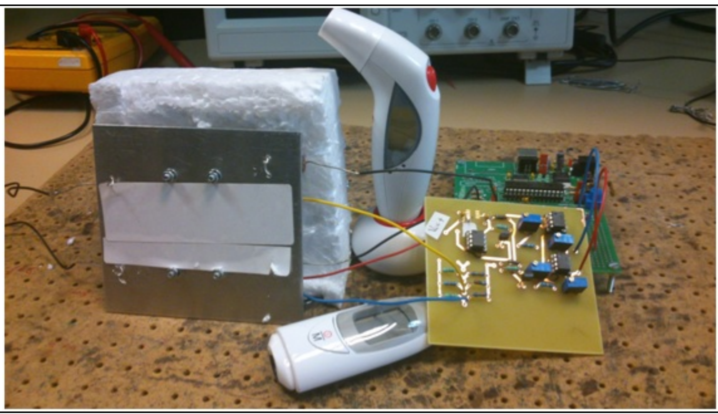

Figure 2. Photo of the prototype (second incarnation). The casing is missing, and the insulation is substituted by a simple Styrofoam layer.

3.1 Results.

Due to space limitation, a summary of the finding will be reported here.

TEST 1 was shown up to be the best verification procedure to be done in the hospital plant for the interim checks, once the other uncertainty contributions were evaluated.

TEST 2 allowed to evaluate the “drift” of the displayed value in each TIF for the same reference temperature on the prototype.

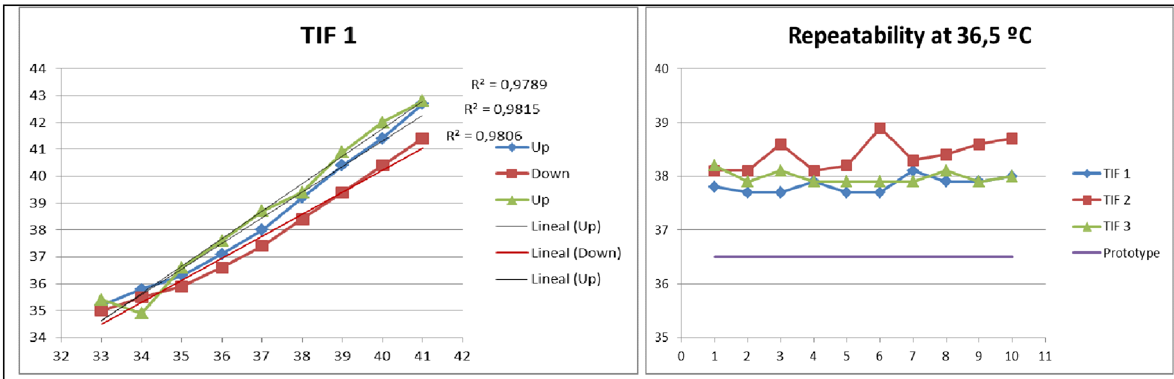

Figure 3. Results of TEST 1 with TIF 1, and TEST 2 with the three TIF's.

TEST 3 showed how the angle introduces a high distortion on the measurement, dealing with a rising contribution to the uncertainty, from TIF 1 to TIF 3.

TEST 4 did show how important is to keep the thermometer not further than 2 cm from the skin, as it has a big influence on TIF 2 and TIF 3. If the measurement is done carefully into the range of 1 cm approximately from the skin, the answer of each thermometer is comparable.
TEST 5 resulted in a small contribution to be taken into account if the ambient conditions may vary more than 5ºC, dealing with a much smaller uncertainty, as shown in the following budget.

Table 2. Drift and verification Uncertainty evaluated for each thermometer with the developed prototype

DEVICE	Uncertainty (k=2)	Drift	Main contribution	Second contribution	Uncertainty (no amb. Infl.)
TIF1	± 2,4	1,3	Ambient. Cond.	Linearity of the TIF	± 1.9
TIF2	± 3	1,9	Ambient. Cond.	Angle influence	± 2,7
TIF3	± 3,1	1,5	Angle	Ambient. Cond.	± 2,8

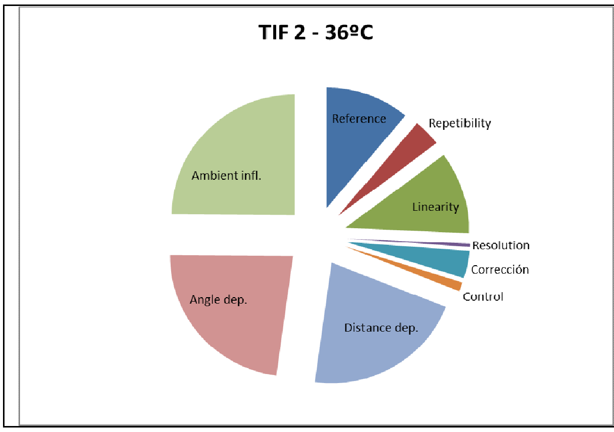

Figure 4. Example of the detailed graphical uncertainty budget for TIF 2.

4. Conclusions

In order to verify the correct operation of infrared clinical thermometers, we developed and implemented a system suitable to carry over a routine evaluation of the instruments in a simple and effective way. To test the system, we analyzed three thermometers for their metrological characteristics and presented the results here.

The results obtained in terms of uncertainty are quite on line on these found in literature [7] if only measurements carried over in "perfect" conditions are analyzed --- where the accuracy estimated with k=1 can be considered as low as ±0.5 ºC; however it is quite evident (see table 2) that in practical use, it is easy to find uncertainties of the order of ±2 ºC. The influence of the ambient conditions and the angle of sight of the optic are the main source of errors in our tests, so they have to be taken into account in field usage.

Summarizing, the system can be effectively used for a fast, routinely verification of the infrared thermometers. A couple of the tests (especially TEST 2) can be performed in little time by unspecialized or nursing personnel and can give a faithful hindsight on the correct operation of the instruments.

5. Acknowledgements

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6. References

[1] F.A. Fernández, 2011, *private communication,* in process of publication

[2] S. F. Tsai, "Comparison Measurements of Infrared Ear Thermometers Against Three Types of Blackbody Sources", Int J Thermophys (2010) 31:1821–1831

[3] Igor Pušnik et al, "Comparison of Blackbodies for Calibration of Infrared Ear Thermometers", Int J Thermophys (2011) 32:127–138

[4] M. L. Cohen, "Measurement of thermal properties of human skin, a review", The Journal of Investigative Dermatology, 69:333-338, 1977

[5] Kimio Otsuka et al, "Imaging of Skin Thermal Properties with Estimation of Ambient Radiation Temperature", IEEE Eng. Med. Bio, Nov/Dec 2002, 49-55.

[6] M. J. Martín et al, "Influencia de la temperatura ambiente y del material de las aperturas en calibraciones de termómetros de radiación de infrarrojo (8-14 μm) de 0 °C a 30 °C" (in Spanish: Influence of ambient temperature and openings material in calibrations of infrared radiation thermometers (8-14 μm) from 0 ° C to 30 ° C), Congreso Español de Metrología, junio 2009.

[7] J. A. Kistemaker et al., "Reliability of an infrared forehead skin thermometer for core temperature", Measurements Journal of Medical Engineering & Technology, Vol. 30, No. 4, July/August 2006, 252 – 261